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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,582	10/27/2003	Robert W. Etheredge III	963	1098

7590 11/17/2005
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EXAMINER

CHAPMAN, GINGER T

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/693,582	Applicant(s) ETHEREDGE, ROBERT W.	
	Examiner Ginger T. Chapman	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign mentioned in the description: 35 “barrier layer” as described p. 7 ¶ 4, l. 5; p. 8, l. 8.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character not mentioned in the description: **33**.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 1, 2 and 3 are objected to because of the following informalities:

Claim 1 recites the limitation "the stoma port" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the pouch chamber" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites the limitation "the pouch walls" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites "to receive he bodily waste" in line 3. Examiner considers this a typo and therefore reads the line as "to receive the bodily waste" in accordance with the antecedent basis provided for the bodily waste in line 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turner (US 4,871,046) in view of Worrell, Sr. (US 4,131,195).

With regard to claim 1: As seen in Figures 2-5, 7 and 8, Turner discloses a product comprising a dispenser container (30) having therein a roll (32) of pouches (10), the adjacent pouches (10) in the roll (32) being separated by a fracture line (26) to facilitate easy separation of the lead pouch (10) in the roll (32) from the other pouches (10) in the roll (32), each of the pouches (10) having two opposed flexible sheets (12, 22) of a flexible liquid-impermeable material (col. 3, l. 22) sealed together along their respective edges (16, 18) to provide a liquid-impermeable enclosure defining an expandable chamber (col. 3, ll. 6-8); the pouch having an opening (20) substantially centrally disposed between two opposed edges (12, 14) of one of the sheets (12) defining the opening (20) (col. 3, ll. 12-14), thereby permitting products to pass through the port (20) to within the pouch (10) chamber.

Turner discloses the opening but does not disclose the opening defined by fracture lines. Worrell teaches the fracture lines. As seen in Figure 1, Worrell teaches the pouch (10) having

fracture lines (22; col. 4, l. 13) substantially centrally disposed (fig. 1) between two opposed edges of one of the sheets (20) defining an opening (22) which is revealed when the fracture lines are broken to separate the material between the fracture lines (col. 3, ll. 65-68), thereby permitting products to pass through the port (22) of the pouch (10). Worrell states that the benefit of making the opening with the fracture lines is that the moisture-impervious protective sheet over the opening provides a seal over the opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the opening of Turner with fracture lines as taught by Worrell in order to provide a protective seal over the opening thereby providing a sanitary product to the user of the pouch.

The combination of Turner and Worrell disclose the invention substantially as claimed except for the manner in which the device is intended to be employed; it has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner (US 4,871,046) in view of Worrell, Sr. and further in view of Liese, Jr. et al (US 2003/0171737).

With regard to claims 2 and 4, the combination of Turner and Worrell disclose the dispenser roll of pouches but fail to disclose a barrier flange. As seen in Figures 1 and 6, Leise, Jr, et al teach a barrier flange sheet material (4) having an adhesive coating (2) on one side thereof for securing the barrier sheet material (p. 1, [0015], ll. 2-4), the barrier flange material (4)

having a substantially centrally disposed (10) opening (11) defining a stoma port (11) for egress of bodily waste products from the stoma (p. 4, [0077], l. 5); the pouch (p. 4, [0079], l. 2) being releasably secured to the barrier flange with the opening of the sheet of the pouch in alignment with the stoma port in the barrier sheet (fig. 6), whereby bodily waste products emanating from the stoma port will collect through this opening into the cavity of the pouch defined by the pouch walls (p. 5, [0079]). Leise states that the advantage of making the barrier flange with this design is that the barrier material has moisture absorbing and barrier properties and is easy to apply and remove to the wearer's stoma and is cheap to manufacture (p. 1, [0014, 0015]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the barrier flange material of Leise with the pouch of Turner and Worrell

With regard to claim 3, the combination of Turner and Worrell in view of Leise disclose the method for recovering bodily waste products from an ostomate following a colostomy, ileostomy or urostomy surgical procedure by securing an ostomy pouch for collecting the bodily waste products to an ostomate's skin to receive the bodily waste products discharged from the ostomy (p. 2, [0024-0028]). It is considered normal and usual operation to recover bodily waste from an ostomate by securing an ostomy pouch for collecting the bodily waste products to an ostomate's skin to receive the bodily waste products discharged from the ostomy, therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device as disclosed to perform the method for recovering bodily waste from an ostomate since it has been held that the prior art inherently performs a claimed method when that prior art meets the structural limitations of the article of the claimed invention and is used in normal and usual operation. MPEP § 2112.02.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Teaster (US 5,987,645) discloses a dispenser roll of perforated pouches (Fig. 7). Grissmeyer et al (US 6,635,077) discloses a dispenser roll (fig. 3) of pouches with centrally disposed perforated openings (fig. 7).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ginger Chapman
Examiner, Art Unit 3761
11/11/05



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

